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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

HAND, MELANIE JO

ART UNIT PAPER NUMBER

3761

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,021

Applicant(s)

SHEHADA, RAMEZ EMILE
NECOLA

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
4a) Of the above claim(s) 16-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>various (3)</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Claims 16-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 4, 2005.

Priority

Acknowledgment is made of applicant's claim for priority under copending Provisional Application Nos. 60/445,714 filed on February 7, 2003 and 60/453,009 filed on March 6, 2003.

Information Disclosure Statements

The information disclosure statements (IDS) submitted on January 4, 2005, March 31, 2005 and June 15, 2005 were filed after the mailing date of the Application on February 9, 2004. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiddian-Green (U.S. Patent No. 6,334,064).

With respect to **Claims 1,2**: Fiddian-Green teaches a tonometric catheter sensing apparatus comprising catheter 20 with tubing 22 having inner and outer walls and sensors 42 bonded to said outer wall and further comprising balloon-like membrane 36 fitted over the closed end of tubing 22. (Fig. 1) (Col. 5, lines 6-8,16)

With respect to **Claim 4**: Fiddian Green teaches that sensors 42 are enclosed by balloon 36 (Col. 5, lines 16,17,40-42) and as can best be seen from Fig. 1, balloon 36 and sensors 42 are located at approximately the same position along tubing 22.

With respect to **Claims 5 and 6**: Fiddian-Green teaches that sensors 42 detect properties indicative of pH and/or temperature, and can measure the partial pressures of hydrogen, oxygen, or carbon dioxide in the tissue environment. (Col. 5, lines 33-35, 40-42)

With respect to **Claim 7**: Fiddian-Green teaches plural openings 74 or 274 through which a stomach or bladder may be aspirated. (Col. 6, lines 57-59, Col. 10, lines 32-34)

With respect to **Claim 8**: Fiddian-Green teaches lead 164 that outputs a voltage signal indicating a partial pressure of a gas, said voltage signal being fed to an analog-to-digital converter to a microcomputer 172 coupled to a CRT monitor 180. (Col. 7, lines 66,67, Col. 8, line 2, 9-11, 24-27)

With respect to **Claim 9**: Fiddian-Green teaches a pump means (not shown) for continuous or intermittent aspiration of the aspirating medium that fills sample chamber 40 which is defined by the inner surface of balloon membrane 36. (Fig. 1) (Col. 9, lines 41-46)

With respect to **Claim 10**: Fiddian-Green teaches a separate exterior gas analyzing means (not shown) to determine the partial pressure of a gas from a sample of aspirating medium from sample chamber 40. (Col. 9, lines 46-51)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Green ('064) in view of Wittes et al (U.S. Patent No. 3,680,562).

With respect to **Claims 11 and 15**: Fiddian-Green does not teach an anchor for stabilization of catheter 20 relative to tissue in a body cavity. Wittes teaches a catheter 32 comprising a sheath 38 bifurcated into half-tube wings 40,40' that serves as an anchoring means. Since Wittes teaches that catheter 32 is indwelling and designed to contact tissue, it would be obvious to one of ordinary skill in the art to modify the catheter 20 taught by Fiddian-Green to be fitted with a sheath as anchoring means as taught by Wittes.

With respect to **Claim 12**: Wittes teaches that bifurcated wings 40,40' are bent away from catheter tube 28 and affixed to the skin to anchor catheter 32 via sutures after said tubing is implanted within a patient's bladder.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Green ('064) in view of Torre et al (U.S. Patent Application Publication No. 2002/0055757).

With respect to **Claim 13**: Fiddian-Green does not teach a first loop extending from the surface of catheter tubing 22. Torre teaches an intragastric endoscope 10 having a loop on its surface for manipulation, deflation and/or removal of said endoscope. (¶ 0016) Since Fiddian-Green is also teaching a device for gastro-intestinal use, Examiner is concluding that the methods employed to manipulate each device by Fiddian-Green (balloon 36) and Torre (surface loop) are substantially equivalent. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Green ('064) in view of Schoolman (U.S. Patent No. 5,215,539).

With respect to **Claim 14**: Fiddian-Green does not teach that adhesive is disposed on the surface of catheter 20. Schoolman teaches a vacuum strip apparatus for surgical incisions comprising an elongate hollow strip 6 comprising a plurality of openings 28 (Col. 4, lines 61-66) and double-sided adhesive tape 41 on its engagement surface 39 for adhesion to a patient's skin 22. (Fig. 1) (Col. 5, lines 16,17,25-30) Examiner is concluding that the methods employed to anchor each device by Fiddian-Green (balloon 36) and Schoolman (adhesive tape on a tissue engagement surface) are substantially equivalent. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.